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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,017	01/05/2001	D. Wade Walke	LEX-0115-USA	4534

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	14

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/755,017	Applicant(s) WALKE ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 February 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Elizabeth C. Kemmerer

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-8*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-8 are rejected under 35 U.S.C. § 101 (utility) and 35 U.S.C. § 112, first paragraph. Applicant asserts that the human olfactory receptor 2B6, such as NGPCR, would be recognized by those of skill in the art as having a particular utility for its biological role and as a drug target. Applicant argues that agonists and antagonists directed at this NGPCR could effect feeding behavior and thus potentially address obesity, anorexia, or cachexia and other feeding disorders. Applicant's arguments have been fully considered but are not found to be persuasive. Tthe human olfactory receptor 2B6 (Hs6m1-32), which Applicant asserts the polypeptide of the instant application is 100% homologous to, has not been well characterized in the art as an odorant receptor. Since the human olfactory receptor 2B6 has no functional or structural characteristics described in the art, the polypeptide of SEQ ID NO: 2 of the instant application has no credible, specific and substantial asserted utility or a well established utility. Additionally, one skilled in the art would not readily use the claimed nucleotide sequence of SEQ ID NO: 1 to make protein to be used for, for example, tissue-typing or idenification of agonists and antagonists, in a real world sense since the protein is not specific to one tissue and is not associated with any disease or disorder. Also, evidence of mere expression in a cell or tissue is not tantamount to a showing of a role in any human diseases. There is also no disclosure that the claimed polynucleotide encoding the NGPCR polypeptide is expressed at altered levels or forms in any specific, diseased tissue or cell relative to control healthy tissue or cell. Therefore, the skilled artisan would not know how to make and/or use the claimed invention in its full scope. Applicant also contends that the specific utility of the sequences of the present invention is evidenced in the sequence localization to a specific region of the human chromosome and identification of functionally active intron/exon splice junctions. Applicant's arguments have been fully considered but are not found to be persuasive. The specification of the instant application does not disclose the region of the human chromosome the nucleic acid sequence of SEQ ID NO: 1 localizes to or any disease locus it may be linked to. The specification also does not identify functionally active intron/exon splice junctions.

Furthermore, since Applicant has not provided evidence to demonstrate that the NGPCR polynucleotide has a credible, specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

It is noted that regarding all other arguments for 35 U.S.C. § 101 and § 112, first paragraph in the response of 28 February 2003, no substantially new arguments have been presented, and thus the rejections are maintained for reasons of record.

Claims 1-2 and 5-6 remain rejected under 35 U.S.C. § 112, first paragraph (enablement and written description) for the recitation of an isolated nucleic acid molecule comprising at least 80 contiguous bases of the nucleotide sequence described in SEQ ID NO: 1 or an isolated nucleic acid molecule comprising a nucleotide sequence that encodes at least 50 contiguous amino acids of the polypeptide sequence shown in SEQ ID NO: 2.